UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ERFINDERGEMEINSCHAFT UROPEP GBR, Plaintiff, vs. ELI LILLY AND COMPANY, and BROOKSHIRE BROTHERS, INC., Defendants.	Court File No.: 2:15-cv-01202-WCB **JURY TRIAL DEMANDED**

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Eli Lilly and Company ("Lilly") hereby moves for the exclusion of evidence and argument that is irrelevant, confusing, prejudicial, or which has not been properly disclosed pursuant to the Federal Rules of Civil Procedure or this Court's Docket Control Orders, namely:

(1) UroPep provided interrogatory responses in this lawsuit that identified the evidentiary basis for its claims of willful infringement, yet UroPep has made completely different arguments in opposition to Lilly's pending motion for summary judgment on willful infringement. UroPep's new arguments are convoluted, misstate the record, and were never before disclosed. If the Court does not grant Lilly's motion for summary judgment, the Court should limit UroPep's evidence at trial on willfulness to the evidence cited in UroPep's interrogatory responses, and exclude all other evidence.

(2) UroPep has repeatedly cited patents in its briefing that are neither related to the asserted patent in this case ("the '124 Patent") nor prior art to the '124 Patent in an attempt to bolster the '124 Patent's disclosure and claims. For example, UroPep has relied upon Lilly's U.S. Patent No. 6,451,807 ("the '807 Patent") in its Corrected Opposition to Lilly's past motions for summary judgment for noninfringement and lack of written description (Dkt. 132 at 14–15, 38–39) and also in the current summary judgment briefing (Dkt. 189 at 1, 13–17). UroPep's attempt to bolster the '124 Patent by reference to unrelated patents with different disclosures and claims is improper. All such arguments should be excluded.

(3) UroPep has signaled that it intends to argue that the '124 Patent is entitled to a "presumption of validity" before the jury. As other district courts have found, such arguments are confusing, prejudicial and improper as the Court will instruct the jury on the applicable burden of proof for Lilly's invalidity challenge, which addresses the presumption. This Court should bar UroPep from further arguing that the '124 Patent is, additionally, presumed valid.

I. LEGAL AUTHORITY

Under the Federal Rules of Evidence, the Court may exclude evidence that is not relevant. Relevant evidence "(a) [] has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. "Irrelevant evidence is not admissible." Fed. R. Evid. 402. Even if relevant, the Court may exclude evidence if its probative value is substantially outweighed by the danger of unfair prejudice. Fed. R. Evid. 403.

The Court also possesses wide discretion to exclude untimely-produced documents and opinions. Thus, Federal Rule of Civil Procedure 26(a)(2)(B) requires expert reports' disclosure of, among other things: "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; [and] (iii) any exhibits that will be used to summarize or support them[.]" A party must supplement Rule 26(a) disclosures "in a timely manner." Fed. R. Civ. P. 26(e)(1)(A). Subject to the Court's discretion, Rule 37(c)(1) provides that the failure to provide information "as required by Rule 26(a) or (e)" may result in the exclusion of the information for use at trial, "unless the failure was substantially justified or is harmless."

The court's exclusion of evidence will not be reversed unless the party failing to produce the evidence was substantially justified in doing so or the failure was harmless. *See Kam Hing Enters., Inc. v. Wal-Mart Stores, Inc.*, 359 F. App'x 235, 237 (2d Cir. 2010) (citing *Perry v. Ethan Allen, Inc.*, 115 F.3d 143, 150 (2d Cir. 1997); *cf. Sims v. Blot*, 534 F.3d 117, 132 (2d Cir. 2008) ("A district court has abused its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence, or rendered a decision that cannot be located within the range of permissible decisions." (internal citations, alterations, and quotation marks omitted)).

II. ARGUMENT

A. The Court Should Exclude All Undisclosed Argument and Purported Evidence of "Willful" Infringement.

Lilly has moved for summary judgment on (among other things) UroPep's claim that Lilly willfully infringes the '124 Patent. Lilly's motion was based upon discovery in the lawsuit, including UroPep's interrogatory responses that recite the evidence allegedly supporting UroPep's willful infringement claim. Lilly Ex. 31[1], UroPep Interrogatory Responses, at 12–13. In its opposition brief, UroPep makes limited reference to its discovery responses or the record evidence, but instead makes a wide range of accusations that it never before made in the case. *See* UroPep's Comb. Opp. Br. (Dkt. 189) at 29–31. Many of UroPep's new arguments consist of purported (and wrong) accusations regarding Lilly's conduct during the *Markman* process or other Court hearings. There is no basis for any of this asserted new "evidence" to be introduced before the jury. If Lilly's summary judgment motion is not granted, UroPep's willfulness case at trial should be limited to the evidence in its interrogatory responses—nothing more.

Under the Supreme Court's recent decision in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923 (2016), a court should consider "[t]he subjective willfulness of a patent infringer, intentional or knowing . . . without regard to whether his infringement was objectively reckless." *Id.* at 1933. Willful infringement claims are not supported in a typical patent infringement case, such as the one here, but are reserved for those involving "egregious infringement behavior" that has been described as "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Id.* at 1932. To determine whether an accused infringer's conduct was subjectively willful, the Court must

[1] All citations to Lilly Exhibits ("Lilly Ex.") are those submitted in Lilly's Joint Appendix in support of its pending summary judgment and *Daubert* motions. Citations to UroPep Exhibits ("UroPep Ex.") refer to UroPep's submissions with its pending partial summary judgment motion and oppositions to Lilly's recent filings.

"measure[]" the accused infringer's "culpability . . . against the knowledge of the actor at the time of the challenged conduct." *Id.* at 1933. The Supreme Court made clear that enhanced damages "should generally be reserved for egregious cases typified by willful misconduct" and not awarded in "garden-variety cases." *Id.* at 1934–35.

To support its allegations of willfulness, UroPep's interrogatory responses asserted only that (1) it notified Lilly of an earlier patent (UroPep's "'061 patent"), which is not asserted in this case; (2) it notified Lilly of the '124 Patent in October 2014, after the '124 Patent issued; and (3) Lilly has continued to promote the sale of Cialis® to treat the signs and symptoms of BPH. Lilly Ex. 31 at 12–13. UroPep concedes that the promotion of Cialis® does not infringe the '061 patent, and thus providing notice of the '061 patent is irrelevant to whether Lilly allegedly willfully infringed the '124 Patent. *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("To willfully infringe a patent, the patent must exist and one must have knowledge of it." (emphasis omitted)). Without the irrelevant argument about notifying Lilly of the '061 patent, UroPep's willfulness argument boils down to that it notified Lilly of the '124 Patent and Lilly continues its sale of Cialis®.

Lilly, however, was already selling Cialis® for the treatment of the signs and symptoms of BPH nearly 3 years **before** the '124 Patent issued.[2] "A finding of willful infringement requires knowledge of the patent, and activity begun without knowledge of the patent generally cannot form the basis for a finding of willfulness." *AdvanceMe Inc. v. RapidPay, LLC*, 509 F. Supp. 2d 593, 608 (E.D. Tex. 2007).

Conscious that its evidence of willful infringement falls far short of the standard, UroPep created a new set of arguments in its recent summary judgment opposition brief, asserting, among other things, that Lilly did not meet the Court's Docketing Orders or took unreasonable

[2]The FDA approved the use of Cialis to treat BPH on October 6, 2011. The '124 Patent issued on July 29, 2014.

claim construction positions. *See* Comb. Opp. Br. (Dkt. 189) at 29–31. None of these allegations are in UroPep's interrogatory response that discloses the grounds for UroPep's willfulness case. Lilly Ex. 31 at 12–13. They also misstate the record: as the Court may recall, the Court invited the earlier round of summary judgment briefing. Lilly Ex. 55, *Markman* Tr., at 8:7–11 (noting that the Court would be "interested in hearing why that is not a purely functional description that is subject to analysis under the means-plus-function provision Section 112, Paragraph (6). It may not be, but I am going to be interested in hearing why it's not, if it's not."). In fact, as the Court has remarked, "this is a very strange patent." *Id.* at 55:13.

Federal Rule of Civil Procedure 37(c)(1) provides that failure to provide discovery and supplementation "as required by Rule 26(a) or (e)" may result in the exclusion of the information for use at trial, "unless the failure was substantially justified or is harmless." UroPep does not have any justification—much a less substantial justification—for its untimely disclosure of additional materials and theories. Moreover, UroPep's convoluted (and incorrect) tale of alleged procedural violations and disputes over the law will not be understandable to a lay juror, who lacks both the necessary context and background to understand them. It would also essentially make the Court a witness in the case, as UroPep's new arguments implicate the parties' exchanges with the Court at the prior *Markman* (and other) hearings.

UroPep's untimely arguments and allegations are harmful and prejudicial to Lilly. They should be excluded under Rule 37(c)(1), as well as Federal Rule of Evidence 403. If UroPep is permitted to present a willful infringement claim, it should be limited to the evidence disclosed in its interrogatory response. Lilly Ex. 31 at 12–13.

B. The Court Should Exclude Evidence or Argument Regarding Inferences as to the Validity, Infringement, Meaning, or Scope of the '124 Patent Drawn from Unrelated Patents.

Lilly intends to show that the '124 Patent is invalid because it fails to meet requirements for patentability, including the written description and enablement requirements. Rather than focus its response on the disclosures made in the '124 Patent and the sufficiency of those disclosures as compared to the '124 Patent's claims, however, UroPep's arguments to date indicate an intent to confuse the jury by comparing the '124 Patent to other unrelated patents issued to Lilly and third parties (*e.g.*, Pfizer). For example, UroPep has sought to compare the '124 Patent to Lilly's U.S. Patent No. 6,451,807 ("the '807 Patent") in both its present and past summary judgment briefing. *See* UroPep's Corr. Opp. to Lilly's S.J. of Noninfringement and under the Written Descr. Req. (Dkt. 132) at 14–15, 38–39; Comb. Opp. to Lilly's S.J. of Indefiniteness and Noninfringement (Dkt. 189) at 1, 13–17. Among other things, UroPep cited to the '807 Patent to try to demonstrate that the '124 Patent is valid, and/or that its disclosure and claims are normal, acceptable and/or definite. *Id.*

None of these arguments are proper under the law, and all such argument and evidence should be excluded under (at least) Federal Rules of Evidence 401 and 403. As the Court is aware, compliance with the written description and enablement requirements is to be determined based on the disclosure of the '124 Patent. *See, e.g.*, *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The '124 Patent's claims are measured against its disclosure, not the disclosure of other patents. *Id.* Furthermore, what is (or is not) sufficient for the '124 Patent is not affected by the different disclosures and claims in other patents; indeed, even within a *single* patent, each claim stands or falls on its own. *See Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992) (validity of each claim must be considered individually). One cannot compare two unrelated patents, filed months or years apart, and make a meaningful assessment

of the patentability of either one: Their specifications will be different, their filing dates will be different, their prosecution histories will be different, and their claims will be different. The arguments UroPep has made and intends to make again are entirely irrelevant to the issues to be decided by the jury and would be unfair, confusing and unduly prejudicial.

UroPep's own arguments regarding the '807 Patent demonstrate that it, and other patents that UroPep has cited in the course of this lawsuit, are not comparable the '124 Patent. For example, the '807 Patent's claims require a minimum of a 100-fold selectivity ratio in the inhibition of different PDEs, not a 20-fold ratio that the Court has found applicable to the '124 Patent's claims. *See* UroPep Ex. 12 (Dkt. 189-12), '807 Patent, co1. 20:45–56. All other things equal, a 100-fold ratio allows for a greater margin for error in the measurements of IC50 values and excludes more marginal cases than the '124 Patent's stricter 20-fold ratio. The '807 Patent claims further require that the inhibitor has to have an IC50 value of less than 10 nM; the '124 Patent has no minimum IC50 value for potency. Moreover, the claims of the '807 Patent are actually limited to compounds that are 100 times more potent to PDE5 than PDE6 (something UroPep says in its current summary judgment briefing could not be done with any compound in 1997) and 1000 times more selective to PDE1c. The '807 Patent further contains (literally) page after page of specific descriptions of the IC50 assay and test conditions to use. Uropep Ex. 12 (Dkt. 189-12) '807 patent, col. 11:35-15:2. This kind of detail about the specific assay and experimental conditions to use is glaringly absent from the '124 Patent. And, of course, the validity of the '807 Patent (and others) is not at issue in this case so UroPep's underlying assumption for its comparison—that the claims in the '807 Patent and others are valid—has not been tested.

It is for these reasons that UroPep's facile attempt to compare one limited aspect of the '807 Patent and the '124 Patent—*viz.,* they both use IC_{50} values to measure selectivity—is neither relevant nor proper evidence regarding the '124 Patent's scope, disclosure, or validity. But they also point to an additional reason to prevent UroPep from trying to use various other patents with different disclosures and different claims to try to prop up the validity of the '124 Patent. In order to even try to understand UroPep's comparison argument(s), one would need to fully understand the disclosures of patents that are not in this case.

Indeed, such evidence would be confusing to a lay jury, to say the least, assuming it could be done at all. It is difficult enough for a juror to understand complicated legal concepts as written description and enablement, without having the further confusion of introducing the *unrelated* patents of Lilly or others into the mix. Moreover, there is no expert witness in the case who will (or could) lead the jury through such a detailed discussion, as both side's experts have (rightly) focused their review on the patent in suit and the prior art, not extraneous patents that are not part of the claims and defenses that will be tried.

The '124 Patent stands on its own terms, and not on the shoulders of any of the other, unrelated patents. The Court should preclude any argument, evidence, testimony, insinuation, reference, or assertion relating to unrelated patents of Lilly or others in connection with any claim or defense of validity, invalidity, meaning or scope pursuant to at least Fed. R. Evid. 401 and 403.

C. The Court Should Preclude UroPep from Referring to a "Presumption of Validity" at Trial.

Courts routinely preclude parties from referring to a presumption of validity at trial and prefer simply to explain the parties' respective burdens of proof. *Chiron Corp. v. Genentech, Inc*., 363 F.3d 1247, 1258–59 (Fed. Cir. 2004) (affirming district court decision not to instruct

jury on the presumption of validity because the jury had applied the clear and convincing evidence standard); *Alloc, Inc. v. Pergo, Inc.*, No. 02-C-0736, 2007 WL 5289735, at *1 (E.D. Wis. Nov. 21, 2007) ("In the interest of making concepts as clear to the jury as possible, the court will direct that the parties refrain from referring to the 'presumption of validity,' since the parties may refer to the same concept as the Alloc Parties' burden of proof."); *Voda v. Cordis Corp.*, No. CIV-03-1512-L, 2006 WL 5347777, at *3 (W.D. Okla. May 10, 2006) (precluding reference to a presumption, instead instructing jury regarding burden of proof); *Server Tech., Inc. v. Am. Power Conversion Corp.*, No. 3:06-CV-00698-LRH, 2014 WL1308617, at *4 (D. Nev. Mar. 31, 2014) (same); *see also Avia Grp. Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988) (the presumption of validity "does not constitute 'evidence' to be weighed against a challenger's evidence").

The instructions to the jury regarding the parties' respective burdens of proof—specifically, Lilly's burden of proving invalidity by clear and convincing evidence—is sufficient without being bolstered by evidence or argument regarding a "presumption of validity" that suggests an additional, and perhaps even higher, standard of proof than clear and convincing evidence. This Court should bar references to the "presumption of validity" for the reasons stated in prior cases and in accordance with Rule 403.

Dated: February 7, 2017

By: /s/Jon B. Hyland

Jon B. Hyland
BARNES & THORNBURG LLP
2100 McKinney Avenue, Suite 1250
Dallas, Texas 75201
Telephone: (214) 258-4123
jon.hyland@btlaw.com

Todd G. Vare
Jeff M. Barron
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, Indiana 46204
Telephone: (317) 231-7735
todd.vare@btlaw.com
jeff.barron@btlaw.com

Felicia J. Boyd (admitted pro hac vice)
BARNES & THORNBURG LLP
225 South Sixth Street, Suite 2800
Minneapolis, Minnesota 55402
Telephone: (612) 333-2111
felicia.boyd@btlaw.com

Attorneys for Defendant
Eli Lilly and Company

CERTIFICATE OF CONFERENCE

The undersigned certifies that a meet and confer was held on February 2, 2017, between counsel for the parties, at which time counsel discussed various potential motions in limine. Agreement was reached on certain of the issues, but not all of them. Plaintiff informed Defendant that this motion is OPPOSED.

/s/ Jon B. Hyland
Jon B. Hyland

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 7th day of February, 2017.

/s/ Jon B. Hyland
Jon B. Hyland